UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Laboratories, Inc., et al.*, 02-CV-12086-PBS	CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris

ABBOTT LABORATORIES, INC.'S SEPARATE MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS MONTANA'S SECOND AMENDED COMPLAINT

Montana contends that Abbott fraudulently inflated the AWPs and reduced the rebates for over 300 drugs, including many multiple-source drugs. *See* Mont. Compl. App. A. Yet Montana's prolix pleading is riddled with inconsistency and inaccuracy, including the following:

- Montana accuses Abbott of falsely inflating Best Price and Average Manufacturer's Price ("AMP") to reduce rebate payments. But non-innovator multiple-source drugs have no Best Price, and inflating AMP can only *increase* the rebate payments a manufacturer must pay for those drugs.
- Under many reimbursement methodologies, multiple-source drugs are paid at a flat rate. This renders AWP manipulation irrelevant. Montana does not, however, identify when a particular drug is reimbursed at a flat rate and when it is paid based on individual AWPs, even in Medicaid where the State is the payor.
- Montana claims that it was fooled into believing that AWPs represented market prices. In fact, Montana had actual knowledge of market prices pursuant to its participation in the Medicaid Rebate Program, negating this critical allegation.
- Montana claims to identify a "spread" between AWP and market prices for many Abbott drugs, but does not identify any fraudulent conduct regarding these drugs.
- Montana alleges that Abbott competed on the "spread" but fails to identify any drugs against which Abbott's brand name drugs might compete.

As explained below, these shortcomings require that the claims against Abbott be dismissed.

I. Rebate Claims For Non-Innovator Multiple-Source Drugs Should be Dismissed

Montana alleges that manufacturers failed to report accurate Best Price and Average Manufacturer's Price ("AMP") data to CMS as required under contracts and statutes governing the Medicaid Rebate Program. *See* Mont. Comp. ¶¶ 603-634. Specifically, Montana alleges that manufacturers "reported higher prices" for AMP and Best Price by failing to include discounts and other reductions in price. *See id.* ¶ 612. If true, such misreporting would *increase*, not decrease, the rebates paid on non-innovator multiple-source drugs. Accordingly, all rebate claims relating to non-innovator multiple-source drugs should be dismissed.

The per-unit rebate for "single-source drugs" and "innovator multiple-source drugs" is calculated as the greater of (a) the difference between AMP and Best Price or (b) 15.1% of AMP,

plus an upward adjustment for inflation, if necessary. *See* 42 U.S.C. § 1396r-8(c). The per-unit rebate for "non-innovator multiple-source drugs," by contrast, is calculated as 11% of AMP. *Id.* Thus, an artificially high Best Price cannot reduce the per-unit rebate for non-innovator multiple-source drugs. Moreover, the exclusion of discounts from the calculation of AMP would *increase* the rebates paid by a manufacturer of such drugs to the states. Accordingly, all rebate claims asserted by Montana relating to non-innovator multiple-source drugs fail as a matter of law.

Because Montana's rebate claims fail as to non-innovator multiple-source drugs, this Court should dismiss rebate claims as to *all* Abbott drugs named in the Second Amended Complaint ("Complaint"). Despite naming over 300 Abbott drugs, Montana does not identify which rebates are calculated based on Best Price and which are based exclusively on AMP. (Most of the Abbott products named in the Complaint are non-innovator multiple-source drugs; as to other defendants, Abbott cannot say.) As a result of the Complaint's ambiguity, the Court cannot determine which of the rebate claims to dismiss. Under Rules 8(a) and 9(b), the Court is not required to guess. All rebate claims should, therefore, be dismissed.

II. All Claims Relating to Multiple-Source Drugs Should be Dismissed

This Court should dismiss all AWP claims relating to multiple-source drugs, regardless whether asserted on a *parens patriae* basis or directly on behalf of Montana Medicaid.

Montana's *parens patriae* claims are asserted on behalf of private payors and Medicare Part B beneficiaries who paid for multiple-source drugs. These claims are substantially identical to those asserted in the Amended Master Consolidated Complaint ("AMCC"). For the reasons set forth in the pending motion to dismiss the AMCC, these claims should be dismissed. *See* Consolidated Memorandum in Support of Defendants' Motion to Dismiss the AMCC at 36-38.

The same reasoning applies to Medicaid reimbursement, where many multiple-source drugs are subject to a flat reimbursement rate in Montana. Montana contends that it establishes a

"maximum allowable cost" ("MAC") as the reimbursement rate for "multiple-source drugs for which there are at least three suppliers." Mont. Compl. ¶ 188. For these drugs, competition based on alleged manipulation of AWP is impossible, just as with multiple-source drugs reimbursed under Medicare Part B. Thus, all Medicaid-related AWP claims should be dismissed to the extent that multiple-source drugs are subject to MACs in Montana's Medicaid program.

Here again, Montana's lack of specificity prevents this Court from dismissing only those claims that are flawed and, instead, requires the dismissal of all AWP-based claims. Although Montana describes the formulae by which reimbursement is calculated in various contexts, the State never identifies which drugs are multiple-source and precisely which drugs are paid under each reimbursement methodology. Montana does not even provide this detail for Medicaid, where the State is the payor. The Court must, therefore, dismiss all AWP-based claims for failure to identify which drugs were reimbursed based on individual AWPs and which were reimbursed based on a flat rate.

III. Montana Knew as a Matter of Law That AWPs Exceeded Market Prices

Montana's actual knowledge of market prices is fatal to all claims of fraud against the State. The central tenet of Montana's claims is that it was fooled by the defendants into believing that AWP represented a true market price. Thus, Montana contends that "[d]efendants prevented the State of Montana and others from knowing what the actual pricing structures of these drugs were." Mont. Comp. ¶ 635. This statement is demonstrably untrue as a matter of law, and that falsity is fatal to Montana's claim of fraud.

Each quarter, Montana receives a per-unit rebate on all drugs reimbursed by its Medicaid program. For single-source and innovator drugs, the rebate is at least 15.1% of AMP; for all other drugs, the rebate is equal to 11% of AMP. 42 U.S.C. § 1396r-8(c). Thus, by performing a simple mathematical calculation, Montana can determine on a quarterly basis either the precise

AMP for a drug or the maximum AMP for the drug. For example, if a non-innovator drug has a per-unit rebate of $1.10, then Montana knows that the AMP for that drug is $10.00. If a single source drug has a per-unit rebate of $1.51, then its AMP must be $10.00 or less.

Because Montana knows AMP, the State *a fortiori* knows an actual market price for the drugs it reimburses. By statutory definition, AMP is the average price at which manufacturers sell their drugs to wholesalers for distribution to retail pharmacies. 42 U.S.C. § 1396r-8(k)(1). By simply comparing these two numbers, Montana can determine with mathematical certainty a "spread" between AWP and market price for every drug it reimburses. Such precise knowledge merely confirms that which has been publicly discussed for decades: AWP exceeds providers' acquisition costs. Montana has been advised of this fact over years of government reports, public statements, lawsuits against states and even a 1996 audit of the Montana Medicaid Program itself, all revealing that AWP exceeds market prices. *See* Cons. Mem. at 13-17.

This knowledge is fatal to Montana's claims. Montana cannot assert fraud if it was aware that AWPs bore "little or not relationship to the drugs' pricing in the marketplace." Mont. Compl. ¶ 173. *See* Cons. Mem. at 14. Returning to the examples above, Montana could not claim to have been defrauded by a $15.00 AWP, knowing that actual market prices were $10.00 or less. As a matter of law, such a fraud claim should be dismissed.

IV. Montana Does not Identify "Fraudulent AWPs" for Abbott's Drugs

Finally, Montana's claims should be dismissed for failing to allege the details of any fraud by Abbott. This Court has ruled that plaintiffs in these cases must identify "the allegedly fraudulent AWP for each drug" purchased. *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003). In the Complaint, Montana cynically complied with this requirement simply by listing page after page of data purporting to show the AWP and the "spread" for over 300 Abbott drugs. *See* Mont. Compl. ¶ 226, Exh. A.

Montana's catalog of Abbott drugs is lengthy but inadequate. Exhibit A, for example, just lists the AWPs for 333 Abbott drugs. As to some of these drugs, paragraph 226 of the Complaint lists the "the spread between AWP and wholesale cost," but never explains what the so-called "wholesale cost" represents. *Id.* ¶ 226. As to an even smaller subset of drugs, Montana submits charts showing a "spread" between AWP and contract prices for specific customers, or between AWP and a "DOJ Determined Actual AWP." *See id.* ¶¶ 224-225, 232.

Montana's data do not satisfy this Court's requirement to allege a "*fraudulent* AWP." The charts do nothing more than identify the existence of a "spread." This proves nothing. If AWP is a list price (as defendants contend), then a "spread" between AWP and market prices exists by definition. If AWP is a calculated average of market prices (as plaintiffs contend), a "spread" still would exist between AWP and approximately one-half of all market prices. Either way, Montana must do more than just point to a "spread" in order to allege fraud as to a particular drug. Otherwise, plaintiffs could allege fraud as to every drug sold in the United States simply by attaching a collection of price lists. Rules 9(b) and 8(a) require more.

V. Montana Does not Allege Competitors for Abbott's Brand Name Drugs

Montana does not identify a competitor for the four single source Abbott drugs named in the Complaint (Calcijex®, Biaxin®, Depakote® and Prevacid®). All AWP-related claims asserted against these drugs should be dismissed for the reasons stated in TAP Pharmaceutical Inc.'s Separate Memorandum of Law in Support of its Motion to Dismiss (incorporated herein).

VI. Conclusion

For the foregoing reasons, as well as those stated in the Consolidated Memorandum and those individual defendants' memoranda that apply to Abbott, this Court should dismiss the State of Montana's Second Amended Complaint as to Abbott.

Respectfully Submitted,

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